

Remarks

I. The Specification and Drawings

Applicants thank the Examiner for the thorough review of the specification and drawings. Responsive to the Office Action objection to the drawings, applicants have amended the specification in paragraph [0017] to mention reference sign 160. Applicants respectfully submit that no new matter has been added.

II. 35 U.S.C. §103

Claims 20, 25 and 26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Published Application No. 2002/0007209 to Scheerder et al. in view of U.S. Patent No. 5,843,117 to Alt et al.. The Office Action states:

Scheerder shows a biomedical device (stent) comprising a first layer having a thickness less than 2 mm (stent diameter disclosed as 0.18 mm (para. 0126) so thickness is inherently less than 0.18 mm) and having a concave surface and a convex surface. The stent is coated with a layer of titanium-nitride on the convex surface and has a thickness of 5 microns. The first layer is disclosed as stainless steel (para. 0126) as opposed to titanium. Alt shows a stent and discloses that the stent may be made of titanium (see paragraph bridging columns 15 and 16). It would have been obvious to one of ordinary skill in the art to form the first layer of Scheerder of titanium as taught by Alt, because titanium is considered equivalent to stainless steel.

Applicants respectfully disagree with the Office Action assertion that “Scheerder shows a biomedical device (stent) ... having a concave surface ...” The paragraph [0126] of Scheerder et al. cited by the Office Action instead states:

[0126] To illustrate the invention a coronary stent of a coil-type design, as described in U.S. Pat. No. 5,183,085 was used. It consisted of a preconditioned, non ferromagnetic, highly polished stainless steel wire (AISI 316L) with a diameter of 0.18 mm.

U.S. Patent No. 5,183,085 in turn teaches the manufacture and use of a “helically coiled wire stent.” Such a helically coiled stainless steel wire would not have a concave surface, in contrast to the Office Action assertion. That is, the wire would have an essentially cylindrical (convex) surface. Coiling the stainless steel wire into a helical shape would not create a concave surface.

Moreover, Scheerder et al. further teach:

[0049] Surface characteristics of metal intraluminal prosthesis are determining the human foreign body response to the intraluminal prosthesis. Therefore optimal surface characteristics are critical for the acute and late patency of an intraluminal prosthesis. To further optimize the cutting surface, specific electrochemical polishing techniques were used to optimize the surface characteristics of intraluminal prostheses. Depending on the material used, specific chemical solutions were developed for optimal electrochemical polishing of prostheses.

...

[0051] Electropolishing is a process by which metal is removed from a work piece by passage of electric current when the work piece is immersed in a liquid media (electrolyte). The work piece is connected to the anodic terminal, while the cathodic terminal is connected to a suitable conductor. Both anodic and cathodic terminals are submerged in the solution, forming a complete electrical circuit. The current applied is direct (DC) current. In this process, the work piece is dissolved, adding metal ions to the solution. When a current passes through the electrolyte, a liquid layer of anodic dissolution products is formed on the surface of the anode; this layer has a higher viscosity and greater electrical resistivity than the bulk of the electrolyte. The thickness of the liquid layer on a rough surface differs from site to site. The current density is non-uniform as result of such non-uniform liquid layer; i.e. it is higher on peaks than in crevices. Thus, peaks dissolve more rapidly than crevices, this, therefore, produces a surface-levelling effect.

In other words, electropolishing, which Scheerder et al. teach is critical, dissolves peaks more rapidly than crevices. Thus each of the filaments 1 of Scheerder et al. would have been expected to have a rounded cross-section, similar to that of a cylindrical wire. A mesh formed of such filaments and shaped as a stent would not have a concave surface, just as a coiled wire would not have a concave surface.

Applicants also respectfully disagree with the Office Action assertion that “It would have been obvious to one of ordinary skill in the art to form the first layer of Scheerder of titanium as taught by Alt et al., because titanium is considered equivalent to stainless steel.” Initially note that it is unclear from this statement whether the Office Action is claiming that the Examiner considers titanium to be equivalent to stainless steel or that any person of ordinary skill in the art considers titanium to be equivalent to stainless steel. If it is the former, applicants respectfully request the Examiner to provide

an affidavit as required by 37 CFR 1.104(d)(2). If it is the latter, applicants respectfully request the Examiner to provide a reference as required by MPEP §2144.03. If the Examiner believes that the cited paragraph of Alt et al. provides support for this equivalence allegation, note that this paragraph also references the use of a polymer, which would also be equivalent to stainless steel under this Office Action reasoning. Applicants respectfully assert that neither stainless steel nor a polymer is equivalent to titanium.

Moreover, The Office Action has provided no incentive for its proposed modification of Scheerder et al. with Alt et al. Simply stating that "titanium is considered equivalent to stainless steel," which applicants traverse, does not provide the incentive required by 35 U.S.C. §103. Note that components which are functionally or mechanically equivalent are not necessarily obvious in view of one another. *Smith v. Hayashi*, 209 USPQ 754 (Bd. of Pat. Inter. 1980). Indeed, as stated in *In re Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002):

When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness. See, e.g., *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351-52, 60 U.S.P.Q.2D (BNA) 1001, 1008 (Fed. Cir. 2001) ("the central question is whether there is reason to combine [the] references," a question of fact drawing on the *Graham* factors).

"The factual inquiry whether to combine references must be thorough and searching." *Id.* It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with. See, e.g., *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124-25, 56 U.S.P.Q.2D (BNA) 1456, 1459 (Fed. Cir. 2000) ("a showing of a suggestion, teaching, or motivation to combine the prior art references is an 'essential component of an obviousness holding'" (quoting *C.R. Bard, Inc., v. M3 Systems, Inc.*, 157 F.3d 1340, 1352, 48 U.S.P.Q.2D (BNA) 1225, 1232 (Fed. Cir. 1998))); *In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2D (BNA) 1614, 1617 (Fed. Cir. 1999) ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."); *In re Dance*, 160 F.3d 1339, 1343, 48 U.S.P.Q.2D (BNA) 1635, 1637 (Fed. Cir. 1998) (there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant); *In re Fine*, 837 F.2d

1071, 1075, 5 U.S.P.Q.2D (BNA) 1596, 1600 (Fed. Cir. 1988) ("teachings of references can be combined *only* if there is some suggestion or incentive to do so.") (emphasis in original) (quoting *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 U.S.P.Q. (BNA) 929, 933 (Fed. Cir. 1984)).

For these reasons also the Office Action has failed to present a prima facie case of obviousness of claims 20, 25 and 26.

III. Allowable Subject Matter

Applicants appreciate the indication that claims 1-19 and 21-24 contain allowable subject matter.

IV. Conclusion

Applicants have amended the specification to mention a reference numeral found in the drawings. Applicants have also shown that the Office Action has not presented a prima facie case of obviousness for the rejected claims. As such, applicants respectfully assert that the application is in condition for allowance, and a notice of allowance is solicited.


Respectfully submitted,

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to MS No Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on December 15, 2004.

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